Registration Decision RD2015-02

Metconazole

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607-D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Registration Decision for Metconazole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Metconazole Fungicide Technical and the associated end-use product, Metlock Fungicide, containing the technical grade active ingredient metconazole, for early season control or suppression of seed- and soil-borne fungal pathogens in canola, rapeseed, carinata, corn and wheat.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-14, *Metconazole*. This Registration Decision[2] describes this stage of the PMRA regulatory process for metconazole and summarizes the Agency's decision, and the reasons for it. The PMRA received no comments on PRD2014-14. This decision is consistent with the proposed registration decision for Metconazole Fungicide Technical and Metlock Fungicide stated in PRD2014-14.

For more details on the information presented in this Registration Decision, please refer to Proposed Registration Decision PRD2014-14, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website.

What is Metconazole?

Metconazole is a triazole fungicide (demthylation-inhibiting fungicide) that inhibits sterol biosynthesis and is currently registered for foliar uses. Metlock Fungicide is a seed treatment fungicide for broad spectrum control of early-season diseases.

Health Considerations

Can Approved Uses of Metconazole Affect Human Health?

Metlock Fungicide is unlikely to affect your health when used according to label directions.

Potential exposure to metconazole may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

The technical grade active ingredient, metconazole, was moderately toxic to rats and highly toxic to mice when given as a single oral dose. It was of low acute dermal toxicity to rats and rabbits and of low acute inhalation toxicity to rats. It was moderately irritating to the eyes and non-irritating to the skin of rabbits. It did not cause an allergic skin reaction in the guinea pigs. The signal words, "DANGER – POISON" and "EYE IRRITANT" have been included on the label in light of these findings.

Metlock Fungicide was of low acute oral, dermal and inhalation toxicity and was minimally irritating to the eye and skin of the rabbit. It did not cause an allergic skin reaction.

Health effects in animals given repeated daily doses of metconazole over longer periods of time were decreased body weights, effects in blood (regenerative anemia) and microscopic changes to the liver, spleen and adrenal glands. There was no evidence that metconazole damaged genetic material. Skin tumours in male mice were observed following oral administration. There was no evidence of cancer in rats.

When metconazole was orally or dermally administered to pregnant rabbits, cranio-facial malformations were observed in fetuses. Limb-flexure malformations were observed in fetuses when metconazole was administered dermally to pregnant rabbits. These effects were observed at doses that were not toxic to the mother, indicating that the fetus is more sensitive to metconazole than the adult animal. Due to the serious nature of these endpoints, extra protective factors were applied during the risk assessment to further reduce the allowable level of human exposure to metconazole.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which the effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and infants less than one year old, the subpopulation that would ingest the most metconazole relative to body weight, are expected to be exposed to less than 56% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from metconazole is not of health concern for all population subgroups.

The lifetime cancer risk from the use of metconazole is not of health concern.

Acute dietary (food plus drinking water) intake estimates for females 13-49 years old were less than 83% of the acute reference dose, and are not of health concern. For all other subpopulations, an acute reference dose was not established; therefore an acute dietary intake estimate is not required.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using metconazole on wheat as a seed treatment are acceptable. MRLs to cover residues of metconazole in/on wheat and commodities in the rapeseed subgroup have been established based on residue data generated following foliar applications. The seed treatment uses of metconazole on wheat and canola are not expected to result in residues exceeding the established MRLs. The results of the radiotracer

study with metconazole as a seed treatment in corn indicate that finite residues of metconazole are not anticipated in corn commodities from seed treatment use of metconazole. Maximum residue limits will be established for corn at the limit of quantitation of the enforcement method. There are no food or feed commodities associated with the uses on carinata and rapeseed under the proposed labels.

Occupational Risks From Handling Metconazole

Occupational risks are not of concern when Metlock Fungicide is used according to the proposed label directions, which include protective measures.

Workers who treat with Metlock Fungicide, or plant treated corn, canola, rapeseed, carinata and wheat seed can come in direct contact with metconazole residues on the skin and through inhalation.

When treating seed with Metlock Fungicide, the label specifies that seed treatment workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. When commercially treating wheat seed with Metlock Fungicide, workers must also wear a respirator. In addition, workers cleaning treating equipment must wear chemical-resistant coveralls over a long-sleeved shirt and long pants. Closed transfer is required for treating seeds in commercial seed treatment facilities and for mobile treaters.

The Metlock Fungicide label specifies that workers must wear a long-sleeved shirt, long pants, and protective gloves when handling treated seed. Workers must also use a closed cab planter when planting treated wheat.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Metconazole Is Introduced Into the Environment?

When used according to the label directions for seed-treatment, metconazole is not expected to pose an unacceptable risk to the environment.

Metconazole can dissolve in water and breaks down slowly in terrestrial and aquatic environments. Metconazole is not prone to surface runoff as treated seeds are buried during planting; however, with heavy rainfall or irrigation it may have a potential to percolate through soil layers and reach groundwater. Specific instructions, therefore, are provided on product labels to minimize potential transfer to groundwater. Metconazole is not likely to accumulate in plant and animal tissues.

When used as a seed treatment, metconazole presents a negligible risk to terrestrial and aquatic organisms since it is unlikely that organisms will be exposed to high enough concentrations to cause harm. However, precautionary hazard statements are required on product labels. When metconazole is used in accordance with the label and the required risk-reduction measures are applied, it is not expected to pose an unacceptable risk.

Value Considerations

What Is the Value of Metlock Fungicide?

This seed treatment product provides early season control or suppression of seed- and soil-borne fungi and insects.

Metlock Fungicide protects the seedling from seed rot, damping off, and/or root rot, as well as seed-borne pathogens in canola, rapeseed, carinata, corn and wheat.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Metlock Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with metconazole on the skin or through inhalation of spray mists, anyone treating seeds with Metlock Fungicide or handling treated seeds must wear a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes. When commercially treating wheat seed, workers must also wear a respirator. In addition, cleaners involved with commercial seed treatment must also wear chemical-resistant coveralls over a long-sleeved shirt and long pants. Closed transfer is required for treating seeds in commercial seed treatment facilities and for mobile treaters. When planting treated seed, workers must wear a long-sleeved shirt, long pants, and protective gloves when handling seed. Workers must also use a closed cab planter when planting treated wheat.

Environment

For metconazole, the currently registered foliar application rates are in the range of 182.4 to 560 g a.i./ha/season while the proposed seed treatment rates are in the range of 0.09 to 1.65 g a.i./ha/season. Therefore, the existing risk mitigation measures required for foliar application are adequate for the proposed use for seed treatment in commercial and on-farm treatment facilities.

No additional precautionary label statements are required for Metlock Fungicide.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-14) are available for public inspection, upon application, in the PMRA Reading Room (located in Ottawa). For more information, please contact the PMRA Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management section of the Health Canada website (Request a Reconsideration of Decision) or contact the PMRA Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.